REMARKS

Claims 34-43 and 50-68 are pending and are currently under consideration. Applicant notes that claim 69 is now withdrawn and reserves the right to pursue the subject matter in a divisional application.

Claim 34 is amended to recite a method of providing an encapsulation device to a desired location, the method comprising: expanding a porous body having a cavity to conform to a shape of a target by introducing a first fluid into an opening in the body, where the porous body comprises at least a first surface and a second surface each forming a portion of the cavity of the porous body, where each of the surfaces engage and conform to respective first and second portions of the target, where the first surface has a permeability different than [[a]] the second surface of the porous body; introducing a second fluid into the porous body to displace the first fluid through the at least the first surface of the porous body differently than the second surface of the porous body; and allowing the second fluid to cure to secure the porous body to the target.

Support for these amendments can be found in Figs. 34 to 45 as well as the accompanying text.

Claim 52 is amended to recite a method of providing an encapsulation device to a desired location, the method comprising: expanding a porous body to conform to a shape of a target by introducing a first fluid into an opening in the body; introducing a second fluid into the porous body to displace the first fluid through the porous body; securing a wire reinforcement to an interior surface of the porous body to assist the porous body in maintaining the shape during delivery, deployment and hydrating of the encapsulation device; and allowing the second fluid to cure to secure the porous body to the target such that the wire reinforcement remains within the porous body.

Support for this amendment can be found in paragraph **[0102]**

No new matter is amended by these amendments.

Rejections under 35 USC § 112

Claims 34-43 and 50-68 are rejected under 35 U.S.C. §112 1st paragraph. The Office Action asserts that support for amendments to 34 and 59, which include "first and second surfaces that each engage and conform to respective first and second portions of the target where the first and second surfaces have different porosities" is not found in the application. The Office Action further asserts that "not all of the surfaces necessarily engage the target and nothing of record appears to support that the surfaces of different porosities necessarily engage and conform to the target so one of ordinary skill would not recognize this as the inventive feature. "

Applicant disagrees. In addition to the previously cited sections of the subject application, paragraph [0094] reproduced below, and also refers to paragraph [0170], though paragraph [0170] discusses a different species, it discusses two surfaces having varying porosities that conform to respective first and second portions of a target:

[0094] Additionally, while ePTFE and porous PET are discussed above as membrane material for use as the encapsulation device, other porous membrane material may be used within the scope of the present invention such as metallic wire mesh or porous Nitinol. More specifically, in one embodiment, the encapsulation device of the present invention may be made from material that is semi-permeable on one side and relatively less permeable or non-permeable on the other side. The more permeable side could be designed to weep some of the more viscous material, such as an adhesive including cyanoacrylate, epoxy, or other bioactive compound, into and/or through the encapsulation device membrane, to preferentially activate or adhere to different areas along the geometry of the encapsulation device. The membrane itself may be dumbbell shaped and have the cavity filled or layered, with channels between the layers filled.

[0170] Alternatively, in accordance with another embodiment of the present invention, the encapsulation device **5901** may be injected with, for example, superporous hydrogel. Similarly, polymethylmethacrylate (PMMA) may be injected in lieu of the superporous hydrogel into the encapsulation device **5901**. PMMA is commonly used as a bone cement, and hardens to a substantial strength when cured. Also, PMMA in an alternate embodiment may be blended with another material to soften it, as desired. Even further alternatively, the encapsulation device **5901** may be configured such that it comprises a porous side and a non-porous side, where the PMMA may be configured to weep through the porous side. In this case, the two porosity design of the encapsulation device **5901** may comprise two sheets bonded together as discussed above in conjunction with **FIGS. 13 and 14**. With the upper porous side design of the encapsulation device **5901**, the PMMA may be weeped and bonded to the bone above, and not below the spinal disk, so that more patient flexibility may be provided as bonding two bones together is spinal fusion.

Clearly the specification provides for encapsulation devices with a first side that is semi-permeable and is relatively less permeable second side. In addition, the specification gives clear support for encapsulation devices that are fully expanded within a cavity in tissue. (See e.g, Figs. 36-42 as well as the accompanying text at paragraph 150).

Rejections under 35 USC § 103 - I

Claims 34-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Porter et al. (US 6,547,804) in view of Strother et al (US 4364392). Applicant disagrees that the Office Action establishes a proper prima face case of obviousness.

The Office Action acknowledges that "Porter et al. remains silent as to the first surface has permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body." The Office Action relies on Strother to remedy this deficiency by stating: "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include a first surface has a permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body as taught by Strother et al on the pore balloon of Porter et al in order to release the saline."

First, Applicant disagrees that the Office Action meets the requirements of the claim with the proposed combination. Claim 34 requires expanding a porous body to conform to a shape of a target a first surface and a second surface each forming the cavity of the porous body, where each of the surfaces engage and conform to first and second portions of a target where the first surface has permeability different than the second surface.

However, Strother does not teach expanding a porous body to conform to a shape of a target and where first and second surfaces of the porous body each engage and conform to first and second portions of a target where the first surface has permeability different than the second surface.

The Office Action points to Fig. 8 of Strother (copied below for convenience).

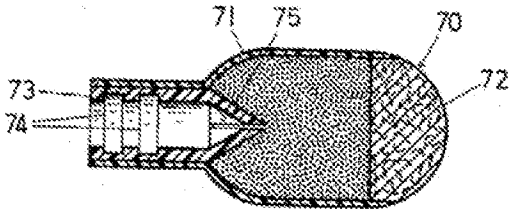

FIG. 8

Material 72 comprises a plug. See Strother col. 6, lines 27 to 46. Applicant is unable to find any teaching or suggestion in Strother that the plug can engage and conform to any

portion of the target. Moreover, the plug of Strother cannot define a cavity of the porous body. Furthermore, there is no teaching that the plug is distensible. Porter clearly states the need for a distensible balloon.

Second, Applicant also reiterates the previous arguments that the combination of Porter and Strother is improper. A prima facie case of obviousness requires some suggestion or motivation to make the proposed modification. The United States Supreme Court made clear that "[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, ***there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness***.'" KSR, 550 U.S. at ____, 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)."

In the present rejection, the Office Action merely states that the combination is made "in order to release the saline". However, this falls short of the requirements set forth by the Supreme Court as well as that of the MPEP, in which section §2143 states: "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit."

In addition to discussing the requirements of the KSR decision, MPEP §2143.01 further states that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then *the teachings of the references are not sufficient to render the claims prima facie obvious*." It is also well established U.S. Patent Law that "[i]f [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (MPEP §2143.01).

Porter, at col. 2, line 43 states that: "[t]he balloon of the invention preferably is both porous and highly distensible. The porous material allows aqueous inflation fluid to pass though the balloon wall at low pressure." Inflation of the Porter balloon at a low pressure is clearly desirable given the device's intended purpose to fill aneurysms or other vascular sites. (See Porter Abstract; col. 3, lines 42-66 to col. 5, line 18). Applicant submits that changing a portion of the Porter device to have a varying porosity will also affect the ability of the device to allow fluid to pass through the balloon wall at a low pressure. Clearly, a varying porosity will affect the pressure within the Porter device. For these reasons alone, applicant

submits that the modification proposed by the Office Action, would change the explicitly stated principle of the Porter device as well as render it unsuitable for its intended purpose.

In view of the above, Applicant requests withdrawal of this rejection and believes that the rejection of claims 35-43 should be withdrawn as well.

Rejections under 35 USC § 103 - II

Claims 52-58 are rejected under 35 U.S.C. §103(a) as being unpatentable over Porter et al. (US 6,547,804) in view of Soltesz (US 6527761). Applicant disagrees that the Office Action establishes a proper prima face case of obviousness.

Claim 52 is amended to recite securing a wire reinforcement to an interior surface of the porous body to assist the porous body in maintaining the shape during delivery, deployment and hydrating of the encapsulation device.

Porter teaches, at col. 1, lines 60 to 63: "[t]he balloon wall material is preferably highly distensible so that it can readily conform to the aneurysm at very low pressure inflation and without distention of the aneurysm." col. 2, line 43, which state that: "[t]he balloon of the invention preferably is both porous and highly distensible." Maintaining the shape during delivery, deployment and hydrating of the encapsulation device contradicts the need of the Porter device to conform to an aneurysm at very low pressure inflation.

Applicant again disagrees that the Office Action establishes a proper prima facie case of obviousness. Additionally, Applicant refers to the Examination Guidelines Update published by the U.S. Patent Office on September 1, 2010 in the Federal Register Vol. 75, No. 169 regarding the 2010 KSR Guideline Update (hereafter "*2010 KSR Examination Guidelines*"). Applicant believes that in view of the following information, the *2010 KSR Examination Guidelines* require that the Office Action withdraw this rejection since the combination proposed by the Office Action cannot support a proper prima facie case of obviousness.

Example 4.6 in the *2010 KSR Examination Guidelines*. This example states that "[p]redictability as discussed in KSR encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. *An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason*

being proffered as to why a person of ordinary skill would have combined the known elements."

Furthermore, the addition a wire reinforcement structure to Porter would appear to defeat the express teachings of Porter or at the very least undermine Porter's teachings. Applicant further submits that proposing a modification negatively affecting the distensible nature of the Porter balloon to maintain conform to an aneurysm contradicts the stated purpose of Porter and thus renders the Porter device unsuitable for its intended purpose.

In view of the above, Applicant believes claims 52-58 patentable over Porter et al. (US 6,547,804) in view of Soltesz (US 6527761).

Rejections under 35 USC § 103 - III

Claims 34-51, 59-61 and 63-68 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chobotov (US 6395019) in view of Porter et al and Strother et al.

Again, applicant believes the Office Action fails to establish a proper prima facie case of obviousness. Applicant notes that the Office Action's proposed combination fails to meet the requirements of the claims.

Claim 34 recites expanding a porous body having a cavity to conform to a shape of a target by introducing a first fluid into an opening in the body, where the porous body comprises at least a first surface and a second surface each forming a portion of the cavity of the porous body, where each of the surfaces engage and conform to respective first and second portions of the target, where the first surface has a permeability different than the second surface of the porous body.

Claim 59 recites a method of providing an encapsulation device to a desired location, the method comprising expanding a porous body to conform to a shape of a target by introducing a first fluid into an opening in the body where the porous body comprises at least one rib on an exterior surface of the porous body and having a larger diameter than the porous body when expanded, where expanding the porous body to conform to the shape mechanically locks the rib against the target, where the porous body comprises a first and a second surfaces that conform to respective portions of the target upon expanding; introducing a second fluid into the porous body to displace the first fluid through at least a first side of

the porous body differently than a second side of the porous body; and allowing the second fluid to cure to secure the porous body to the target.

Regarding claim 34:

Chobotov does not teach a device that has expanding a porous body having a cavity to conform to a shape of a target by introducing a first fluid into an opening in the body, where the porous body comprises at least a first surface and a second surface each forming a portion of the cavity of the porous body, where each of the surfaces engage and conform to respective first and second portions of the target, where the first surface has a permeability different than the second surface of the porous body. In contrast, Chobotov teaches the use of inflatable cuffs that, when deployed, conform to the shape of a vessel. The body of the graft does not conform to the vessel and does not expand by introducing a first fluid into the opening in the body. Instead, the body of the stent deploys upon inflation of the inflatable frame structure **13**.

Applicant reproduces col. 6 lines 46 to 67 (below left) and col. 7, lines 51 to 63 (below right) to support the above arguments.

FIG. 1 shows a perspective view of an endovascular graft **10** having features of the present invention and having a proximal end **11** and a distal end **12**. The graft is supported by an inflatable frame **13** which has a proximal end **14** and a distal end **15** and is shown in its deployed state. The inflatable frame structure **13** has a proximal inflatable cuff **16** at the proximal end **14** and an optional distal inflatable cuff **17** at the distal end **15**. The inflatable cuffs **16** and **17** can be similar in shape when deployed, although the cuffs can conform to the shape of the vessel within which they are deployed, and can have an outside diameter or cross sectional dimension of about 10 to about 45 mm, preferably about 16 to about 28 mm. There is at least one elongated inflatable channel **18** disposed between the proximal inflatable cuff **16** and the distal inflatable cuff **17**. The inflatable frame **13** can be from about 5 to about 30 cm in length, preferably about 10 to about 20 cm in length. Disposed between the proximal inflatable cuff **16**, the distal inflatable cuff **17** and the elongated inflatable channel **18** is a thin flexible layer **21** that forms a longitudinal lumen **22** which can confine a flow of fluid therethrough. The thin flexible layer **21** may be made from the same material as the,

The graft **10** is generally deployed by inflation of the inflatable frame structure **13** with a pressurized material of solid particles, gas, fluid or gel which can be injected through an injection port **33**. The pressurized material may contain a contrast medium which facilitates imaging of the device while being deployed within a patient's body. For example, radiopaque materials such as bismuth, barium, gold, platinum, tantalum or the like may be used in particulate or powder form to facilitate visualization of the graft under fluoroscopy. Fixed radiopaque markers may also be attached or integrally molded into the graft for the same purpose, and may be made from the same radiopaque materials discussed above.

The combination of these references appears to be conclusory to simply address the claim requirements rather than provide some rational reason for modification of Chobotov.

Regarding claim 59:

Chobotov does not teach expanding a porous body to conform to a shape of a target by introducing a first fluid into an opening in the body where the porous body comprises at least one rib on an exterior surface of the porous body and having a larger diameter than the

porous body when expanded, where expanding the porous body to conform to the shape mechanically locks the rib against the target, where the porous body comprises a first and a second surfaces that conform to respective portions of the target upon expanding; introducing a second fluid into the porous body to displace the first fluid through at least a first side of the porous body differently than a second side of the porous body; and allowing the second fluid to cure to secure the porous body to the target.

As noted above, Chobotov does not expand the graft body to conform to the vessel. Chobotov inflates the frames to conform to the vessel. Furthermore, as previously argued, in col. 8, lines 27-44, Chobotov refers to the chambers 58 (that are formed from strips 55) as "fluid tight chambers." Chobotov even states that "[i]f the material of the strips 55 which have been bonded to the tubular structure 56 are of a permeable character, *an additional material may be used to coat the inside of the fluid tight chambers in order to make them impermeable to fluids*." (See Chobotov col. 8, lines 33-37). In lines 37-43), Chobotov further teaches how to make chambers impermeable to fluids. Claim 59 of Applicant's claim requires that the porous body include a rib on an exterior that is mechanically locked against the target when the porous body conforms to the shape of the target. Again, the *porous body* in the claim must displace the first fluid through at least a first side of the porous body differently than a second side of the porous body.

In the rejection, the Office Action concedes that "in order not to destroy the Chobotov reference only the inflatable portions, 55 are substituted so that Chobotov would still function as a graft allowing the carrier fluid to release as taught by Strother et al." However, making such an assumption ignores the fact that Applicant's claim requires that the porous body has a rib on the exterior. The only rib in Chobotov is the inflatable portion **55**. To meet the claim requirements of the porous body, the graft body of Chobotov would need to be porous. Even the Office Action acknowledged that doing so destroys the Chobotov reference.

To reiterate, Chobotov teaches a graft device with an inflatable rib where the graft body is fluid tight. Applicant's claim requires a porous body with a rib on an exterior surface of the porous body.

For the reasons stated above, claims 34-51, 59-61 and 63-68 patentable over Chobotov (US 6395019) in view of Porter et al and Strother et al. Accordingly, applicant believes the rejection of claims 34-51, 59-61 and 63-68 should be withdrawn.

Rejections under 35 USC § 103 - III

Claims 60-62 are rejected under 35 U.S.c. 103(a) as being unpatentable over Chobotov in view of Porter et al and Strother et al as applied to claim 59 above, and further in view of Aboul-Hosn (US 6,976,996).

Applicant disagrees, as noted above, Chobotov fails to meet all of the requirements of claim 59, from which claims 60-62 ultimately depend. The addition of Aboul-Hosn (US 6,976,996) does nothing to address the deficiencies of Chobotov.

For the reasons provided above, Applicant requests withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **TSNMNE00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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